

§ 25.34

§ 25.34 Devices and electronic products.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on a device premarket notification submission under subpart E of part 807 of this chapter.

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

(c) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard.

(d) Approval of a PMA or a notice of completion of a PDP or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device.

(e) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(f) Issuance of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(g) Action on an application for an IDE or an authorization to commence a clinical investigation under an approved PDP.

(h) Issuance of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

(i) Approval of humanitarian device exemption under subpart H of part 814 of this chapter.

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Subpart D—Preparation of Environmental Documents

§ 25.40 Environmental assessments.

(a) As defined by CEQ in 40 CFR 1508.9, an EA is a concise public document that serves to provide sufficient evidence and analysis for an agency to determine whether to prepare an EIS or a FONSI. The EA shall include brief discussions of the need for the proposal, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted. An EA shall be prepared for each action not categorically excluded in § 25.30, § 25.31, § 25.32, § 25.33, or § 25.34. The EA shall focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles and shall be a concise, objective, and well-balanced document that allows the public to understand the agency's decision. If potentially adverse environmental impacts are identified for an action or a group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The use of a scientifically justified tiered testing approach, in which testing may be stopped when the results suggest that no significant impact will occur, is an acceptable approach.

(b) Generally, FDA requires an applicant to prepare an EA and make necessary corrections to it. Ultimately, FDA is responsible for the scope and content of EA's and may include additional information in environmental documents when warranted.

(c) Information concerning the nature and scope of information that an applicant or petitioner shall submit in an EA may be obtained from the center or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA EA guidance documents, which provide additional advice